

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Assaf Govari Confirmation No.: 8637
Appln. No. : 09/882,126
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Title : METHOD FOR MEASURING TEMPERATURE AND OF
ADJUSTING FOR TEMPERATURE SENSITIVITY WITH A
MEDICAL DEVICE HAVING A POSITION SENSOR
Art Unit : 3736
Examiner : Frangemonique A. Smith

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APPEAL BRIEF

i. Real Party in Interest

Biosense Webster, Inc., a California Corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. Status of Claims

Claims 1 – 21 are pending in the case. Claims 1 – 21 have been finally rejected on February 12, 2007 and this Appeal is taken from these claims.

iv. Status of Amendments

No Amendments have been filed after this Final Rejection dated February 12, 2007.

v. Summary of Claimed Subject Matter

As fully supported in Applicant's Specification, for example, Figs. 1A, 1B, 2, 3A, 3B, 4, 5, Table 1 and Page 31, line 6 – Page 34, line 13, Claim 1 of the present invention is directed toward a method for measuring temperature at a site within a patient during a medical procedure comprising the steps of providing a medical device 80 having a position sensor 10 for providing signals used in determining position and/or orientation coordinates of the position sensor 10. Page 9, Lines 8 – 14 and Page 33, Lines 1-5. The medical device 80 is placed within the patient and the position sensor 10 is positioned at the site. Page 33, Lines 1-5. Position and/or orientation coordinates of the position sensor 10 are determined based on the signals provided by the position sensor 10 using a location system 30. Page 9, Lines 8 – 14; Page 13, Lines 20-23; and Page 33, Lines 5-8 And, a temperature measurement signal is provided to the position sensor 10 by the system 30 and the voltage is measured at the position sensor by the system 30. Page 31, Lines 23-28. The system 30 then determines a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system 30). Page 32, Lines 20 – 28 and Table 1, Fig. 3A and Fig. 3B.

Accordingly, the temperature measurement method according to Claim 1 of the present invention provides the physician with great flexibility and avoids having to use separate temperature monitors or temperature sensors such as thermocouples. Thus, by

utilizing the sensor coil 10 in accordance with the present invention, the overall costs of the medical procedure are also reduced. Page 34, Lines 7 – 13.

Claim 13 of the present invention is directed to a method for adjusting for temperature sensitivity of a medical device having a position sensor. Figs. 1A, 1B, 2, 3A, 3B, 4, 5, Table 1 and Page 31, line 6 – Page 34, line 13. The method comprises the steps of providing a medical device 80 having a position sensor 10 for providing signals used in determining position and/or orientation coordinates of the position sensor 10. Position and/or orientation coordinates of the position sensor 10 are determined based on the signals provided by the position sensor 10 using a location system 30. Page 9, Lines 8 – 14; Page 13, Lines 20-23; and Page 33, Lines 5-8 And, a temperature measurement signal is provided to the position sensor 10 by the system 30 and the voltage is measured at the position sensor by the system 30. Page 31, Lines 23-28. The system 30 then determines a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system 30). Page 32, Lines 20 –28 and Table 1, Fig. 3A and Fig. 3B.

Accordingly, the temperature measurement method according to Claim 13 of the present invention provides the physician with great flexibility and avoids having to use separate temperature monitors or temperature sensors such as thermocouples. Thus, by utilizing the sensor coil 10 in accordance with the present invention, the overall costs of the medical procedure are also reduced. Page 34, Lines 7 – 13.

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 1-2, 4-5 and 9-15 have been finally rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,241,724 (Fleischman et al.).

2. Claims 6-8 have been finally rejected under 35 U.S.C. § 103 (a) as being unpatentable over Fleischman et al. in view of U.S. Patent No. 6,569,160 (Goldin et al.).

3. Claims 3 and 16-21 have been finally rejected under 35 U.S.C. § 103 (a) as being unpatentable over Fleischman et al. in view of U.S. Patent No. 5,638,418 (Douglas et al.).

vii. Argument

1. The rejection of Claims 1-2, 4-5 and 9-15 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,241,724 (Fleischman et al.) is improper and without basis and should be overruled.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. *In re Arkley*, 59 CCPA 804, 455 F. 2d 586, 587, 172 USPQ 524, 526 (1972). Thus, in order to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States*, 360 F.2d 954,960, 148 USPQ 298, 301 (Ct. Cl. 1966).

Turning now to the prior art reference, Fleischman et al. is directed to systems and methods for creating lesions in body tissue using segmented electrode assemblies. It is noted that the orientation sensing mechanism 136 described in this reference is actually “means 136 for sensing which electrode element 122, 124, and 126 is in contact with tissue in response to pressure or touch contact between the assembly 120 and tissue.” Column 10, Lines 62-66. It is important to note that the “orientation sensing mechanism 136” is not a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor and is not used in conjunction with a location system for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor such as found with the Applicant’s claimed present invention. Accordingly, this material element of Applicant’s claimed invention of Claims 1 and 13 is completely absent from the teachings of Fleischman et al.

Moreover, Fleischman et al. does not all describe the material element of a

temperature measurement signal that is provided to a position sensor (that is used in determining position and/or orientation coordinates of the position sensor) by the location system. Additionally, Fleischman et al. does not teach measuring voltage at the position sensor by the location system (that is used in determining position and/or orientation coordinates of the position sensor) wherein the location system then determines a resistance value based on the temperature measurement signal and the voltage and a temperature value.

Thus, it is clear that Fleischman et al. fails to disclose material elements recited in Applicant's Claims 1 and 13 and could never anticipate these claims due to the limited teachings found in Fleischman et al.

2. The rejection of Claims 6-8 under 35 U.S.C. § 103 (a) as being unpatentable over Fleischman et al. in view of U.S. Patent No. 6,569,160 (Goldin et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

The invention being claimed in Claim 6-8 of Applicant's claimed present invention is a method for measuring temperature at a site within a patient during a medical procedure comprising the steps of providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor;

placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor); generating an externally applied field at the patient using a generator frequency that is different than the temperature measurement signal, wherein the generator signal is an AC magnetic field (Claim 6) and wherein the generator signal is 3 KHz (Claim 7) and the temperature measurement signal is 4 KHz (Claim 8).

Fleischman et al. discloses systems and methods for creating lesions in body tissue using segmented electrode assemblies. It is noted that the orientation sensing mechanism 136 described in this reference is actually “means 136 for sensing which electrode element 122, 124, and 126 is in contact with tissue in response to pressure or touch contact between the assembly 120 and tissue.” Column 10, Lines 62-66. It is important to note that the “orientation sensing mechanism 136” is not a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor and is not used in conjunction with a location system for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor such as found with the Applicant’s claimed present invention.

It is important to note that Fleischman et al. does not disclose, suggest or even infer a method for measuring temperature at a site within a patient during a medical procedure comprising the steps of providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the

position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor); generating an externally applied field at the patient using a generator frequency that is different than the temperature measurement signal, wherein the generator signal is an AC magnetic field and wherein the generator signal is 3 KHz and the temperature measurement signal is 4 KHz such as found with Applicant's claimed invention of Claims 6-8.

Not only is the scope and content of this prior art reference limited in its teachings, but there are significant differences from the teachings of Fleischman et al. when compared to the novel method steps (as outlined above) of Applicant's claimed present invention. Therefore, one skilled in the art would not be lead by the teaching of Fleischman et al. to experiment with its lesion creating system using segmented electrodes. Thus, contrary to the Examiner's assertions, Fleischman et al. is actually evidence of the non-obvious of the present invention. See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Additionally, there is nothing in Fleischman et al. that indicates that a skilled artisan would have been motivated, where position and orientation coordinate information was required, to provide a medical device with a position sensor that is used for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor by the location system for providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor); and generating an externally applied field at the patient using a generator frequency that is different than the temperature measurement signal, such that the generator signal is an AC magnetic field and wherein the generator signal is 3 KHz and the temperature measurement signal is 4 KHz. Fleischman et al. simply does not describe nor suggest this combination. It is clear that there is no incentive in Fleischman et al. to use such a combination. Therefore,

unless a Declaration under 37 C.F.R. § 1.107(b) is submitted by the Examiner to support this argument, it is not factually supported by the record and may not be the basis for a rejection under 35 U.S.C. § 103. See In re Wagner and Folkers, 152 U.S.P.Q. 552, 559 (CCPA 1967).

According to the Examiner's argument, the combination of Fleischman et al. with Goldin et al. in the rejection was directed toward providing motivation for modifying the structure of Fleischman et al. thereby providing a *prima facie* case of obviousness. However, neither Goldin et al. in combination with Fleischman et al. render the present invention as claimed obvious.

Goldin et al. actually teaches a system and method for detecting electrode-tissue contact. Although Goldin et al. discloses use of a position sensor (location sensor 28), there is no teaching or suggestion in this reference that the location sensor 28 could ever be used in a method for measuring temperature at a site within a patient such as found with the novel method steps of the Applicant's claimed present invention. There are no relevant teachings in either Fleischman et al. or Goldin et al., either alone or in combination with each other, that would ever lead one of ordinary skill in this field to arrive at the Applicant's claimed present invention of Claims 6-8.

Although Goldin et al. teaches use of a position sensor, the reference is directed specifically toward measuring tissue contact only and lacks any teaching or suggestion that its tissue contact method could ever be used to measure temperature at a site within a patient using a temperature measurement signal that is provided to the position sensor by a location system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor); and generating an externally applied field at the patient using a generator frequency that is different than the temperature measurement signal, such that the generator signal is an AC magnetic field and wherein the generator signal is 3 KHz and the temperature measurement signal is 4 KHz.

The claimed present invention of Applicant's Claims 6-8 do not use or claim Goldin et al.'s tissue contact system and method. And, Goldin et al. clearly teaches away from the method steps set forth in Claims 6-8 (in combination with Claims 1 –5) in which the Applicant is claiming. Thus at the time of Applicant's invention, the art actually taught away from the Applicants' invention. Thus, Goldin et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Fleischman et al. to render the present invention obvious.

Thus, there is not only no suggestion or disclosure in Fleischman et al. or Goldin et al. for making the claimed present invention of Applicant's invention, but also, significant differences exist between these limited teachings and Applicant's present invention as claimed. The only suggestion to combine method steps that comprise providing a medical device with a position sensor that is used for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor by a location system for providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor); and generating an externally applied field at the patient using a generator frequency that is different than the temperature measurement signal, such that the generator signal is an AC magnetic field (Claim 6) and wherein the generator signal is 3 KHz (Claim 7) and the temperature measurement signal is 4 KHz (Claim 8) is provided by the Applicant's own Specification. Therefore, these prior art references are being improperly applied by the Examiner, using hindsight reconstruction to pick and choose elements from these references, in the face of contrary teachings in each of these references.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. This burden can only be satisfied by a legal conclusion based on underlying

factual inquiries. See *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ___, 82 USPQ2d 1389 (2007). Accordingly, it is clear that these references are of limited scope and content and provide teachings that are significantly different from Applicant's claimed present invention of a Claims 6-8.

Additionally, even applying ordinary skill and common sense in view of the teachings of Fleischman et al. and Goldin et al., it is evident that one of ordinary skill in this field would not be able to arrive at the novel and nonobvious combination of method steps as set forth in Applicant's claimed present invention. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the PTO. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 6-8.

3. The rejection of Claims 3 and 16-21 under 35 U.S.C. § 103 (a) as being unpatentable over Fleischman et al. in view of U.S. Patent No. 5,638,418 (Douglas et al.) is improper and without basis and should be overruled.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); see *Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

The invention being claimed in Claims 3 and 16-21 of Applicant's claimed present invention is a method for measuring temperature at a site within a patient during a medical procedure comprising the steps of providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position

sensor; placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value through a temperature sensitivity algorithm in the system that uses a resistance drift factor based on the resistance value using the algorithm (Claim 3) and adjusting location information from the position sensor based on the sensitivity position (Claim 14), using position and orientation coordinates (Claim 15), and determining the temperature value at the position sensor by applying a resistance drift factor to the resistance value (Claim 16) and recalling the resistance drift factor from a memory of a signal processor (Claim 17) and establishing the resistance drift factor from a resistance versus temperature profile of the position sensor (Claim 18) and determining the sensitivity at the position sensor (based on position and orientation coordinates set forth in Claim 15) by applying a sensitivity drift factor to the temperature value (Claim 19) and recalling the sensitivity drift factor from a memory of a signal processor (Claim 20) and establishing the sensitivity drift factor from a sensitivity versus temperature profile of the position sensor (Claim 21).

Fleischman et al. discloses systems and methods for creating lesions in body tissue using segmented electrode assemblies. It is noted that the orientation sensing mechanism 136 described in this reference is actually “means 136 for sensing which electrode element 122, 124, and 126 is in contact with tissue in response to pressure or touch contact between the assembly 120 and tissue.” Column 10, Lines 62-66. It is important to note that the “orientation sensing mechanism 136” is not a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor and is not used in conjunction with a location system for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor such as found with the Applicant’s claimed present invention.

It is important to note that Fleischman et al. does not disclose, suggest or even infer a method for measuring temperature at a site within a patient during a medical procedure comprising the steps of providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor; placing the medical device within the patient and positioning the position sensor at the site; determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system; providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor based on the resistance value using the algorithm and adjusting location information from the position sensor based on the sensitivity position, using position and orientation coordinates , and determining the temperature value at the position sensor by applying a resistance drift factor to the resistance value and recalling the resistance drift factor from a memory of a signal processor and establishing the resistance drift factor from a resistance versus temperature profile of the position sensor and determining the sensitivity at the position sensor by applying a sensitivity drift factor to the temperature value and recalling the sensitivity drift factor from a memory of a signal processor and establishing the sensitivity drift factor from a sensitivity versus temperature profile of the position sensor.

Not only is the scope and content of this prior art reference limited in its teachings, but there are significant differences from the teachings of Fleischman et al. when compared to the novel method steps (as outlined above) of Applicant's claimed present invention. Therefore, one skilled in the art would not be lead by the teaching of Fleischman et al. to experiment with its lesion creating system using segmented electrodes. Thus, contrary to the Examiner's assertions, Fleischman et al. is actually evidence of the non-obvious of the present invention. See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Additionally, there is nothing in Fleischman et al. that indicates that a skilled artisan would have been motivated, where position and orientation coordinate information was required, to provide a medical device with a position sensor that is used for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor by the location system for providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a temperature sensitivity algorithm in the system that uses a resistance drift factor and adjusting location information from the position sensor based on the sensitivity position, using position and orientation coordinates, and determining the temperature value at the position sensor by applying a resistance drift factor to the resistance value and recalling the resistance drift factor from a memory of a signal processor and establishing the resistance drift factor from a resistance versus temperature profile of the position sensor and determining the sensitivity at the position sensor by applying a sensitivity drift factor to the temperature value and recalling the sensitivity drift factor from a memory of a signal processor and establishing the sensitivity drift factor from a sensitivity versus temperature profile of the position sensor.

Fleischman et al. simply does not describe nor suggest this combination. It is clear that there is no incentive in Fleischman et al. to use such a combination. Therefore, unless a Declaration under 37 C.F.R. § 1.107(b) is submitted by the Examiner to support this argument, it is not factually supported by the record and may not be the basis for a rejection under 35 U.S.C. § 103. See In re Wagner and Folkers, 152 U.S.P.Q. 552, 559 (CCPA 1967).

According to the Examiner's argument, the combination of Fleischman et al. with Douglass et al. in the rejection was directed toward providing motivation for modifying the structure of Fleischman et al. thereby providing a *prima facie* case of obviousness. However, neither Douglass et al. in combination with Fleischman et al. render the present invention as claimed obvious.

Douglass et al. actually teaches temperature detector systems and methods that are directly related to “integrated circuit temperature detection systems and methods”. Column 1, Lines 35-37. Additionally, it is noted that Douglas et al. is directed toward industrial applications such as temp-cycle test equipment, air conditioning, monitoring equipment and automatic systems such as process control systems. Column 1, Lines 40-52. Even when combined with Fleischman et al., neither Douglass et al. nor Fleischman et al. teach or suggest the combination of novel method steps found with the Applicants claimed present invention. There are no relevant teachings in either Fleischman et al. or Douglass et al., either alone or in combination with each other, that would ever lead one of ordinary skill in this field to arrive at the Applicant’s claimed present invention of Claims 3 and 16 -21.

The claimed present invention of Applicant’s Claims 3 and 16-21 do not use or claim Douglass et al.’s temperature detector systems and methods for integrated circuits. And, Douglass et al. clearly teaches away from the method steps set forth in Claims 3 and 16-21 (in combination with Claims 1 –2 and Claims 13-15 respectively) in which the Applicant is claiming. Thus at the time of Applicant’s invention, the art actually taught away from the Applicants’ invention. Thus, Douglass et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Fleischman et al. to render the present invention obvious.

Thus, there is not only no suggestion or disclosure in Fleischman et al. or Douglass et al. for making the claimed present invention of Applicant’s invention, but also, significant differences exist between these limited teachings and Applicant’s present invention as claimed. The only suggestion to combine method steps that comprise providing a medical device with a position sensor that is used for determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor by a location system for providing a temperature measurement signal to the position sensor by the system; and measuring the voltage at the position sensor by the system; and determining a resistance value based on the temperature measurement signal and the voltage and a temperature value based on the resistance value (through a

temperature sensitivity algorithm in the system that uses a resistance drift factor); and adjusting location information from the position sensor based on the sensitivity position, using position and orientation coordinates, and determining the temperature value at the position sensor by applying a resistance drift factor to the resistance value and recalling the resistance drift factor from a memory of a signal processor and establishing the resistance drift factor from a resistance versus temperature profile of the position sensor and determining the sensitivity at the position sensor by applying a sensitivity drift factor to the temperature value and recalling the sensitivity drift factor from a memory of a signal processor and establishing the sensitivity drift factor from a sensitivity versus temperature profile of the position sensor is provided by the Applicant's own Specification. Therefore, these prior art references are being improperly applied by the Examiner, using hindsight reconstruction to pick and choose elements from these references, in the face of contrary teachings in each of these references.

The PTO has the burden under section 103 of establishing a *prima facie* case of obviousness. This burden can only be satisfied by a legal conclusion based on underlying factual inquiries. See *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ___, 82 USPQ2d 1389 (2007). Accordingly, it is clear that these references are of limited scope and content and provide teachings that are significantly different from Applicant's claimed present invention of a Claims 3 and 16 -21.

Additionally, even applying ordinary skill and common sense in view of the teachings of Fleischman et al. and Douglass et al., it is evident that one of ordinary skill in this field would not be able to arrive at the novel and non-obvious combination of method steps as set forth in Applicant's claimed present invention. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness has not been established by the PTO.

Furthermore, the test for determining whether a reference in the prior art is "analogous" has been set forth by the Court of Appeals for the Federal Circuit (CAFC) in In re Clay, 23 U.S.P.Q.2d 1058 (Fed. Cir., June 10, 1992). The two criteria for determining

whether art is analogous are the following: 1) whether the art is from the same field of endeavor, regardless of the problem addressed, and 2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. See Clay at page 1058.

With respect to the first criteria, Douglass relates to integrated circuits and not in any way related to the medical device field. Clearly, Douglass is not from the same field of endeavor as Applicant's claimed method for measuring temperature at a site within a patient's body using a medical device, i.e. integrated circuits and semiconductors for industrial applications such as temp-cycle test equipment, air conditioning, monitoring equipment and automatic systems such as process control systems versus the medical field in Applicant's claimed present invention resides.

With respect to the second criteria, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem which the invention attempts to solve (see Clay at page 1061). Douglass is particularly concerned with measuring temperature for an integrated circuit in particular industrial applications. In determining whether the second criteria is met, the Court in Clay also looked at whether the particular invention functions in a similar manner to that of the cited reference in question. In the instant case, the integrated circuit temperature measuring system and method of Douglass et al. functions in a radically different manner from the temperature measuring method involving a medical device with position sensor located within a patient's body of Applicant's claimed present invention. Thus, the use of Douglass et al. as prior art is impermissible because Douglass et al. clearly represents non-analogous art. Therefore, the Examiner's rejection is clearly in error and should be overruled.

Therefore, based on the reasons outlined above, it is clear that this obviousness rejection is without merit and should be overruled.

Serial No. 09/882,126

Respectfully submitted,

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viii. Claims Appendix

Claim 1. (Previously Presented)

A method for measuring temperature at a site within a patient during a medical procedure comprising the steps of:
providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor;
placing the medical device within the patient and positioning the position sensor at the site;
determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system;
providing a temperature measurement signal to the position sensor;
measuring voltage at the position sensor;
determining a resistance value based on the temperature measurement signal and the voltage; and
determining a temperature value based on the resistance value.

Claim 2. (Original)

The method according to Claim 1, further comprising determining the temperature value based on an algorithm.

Claim 3. (Original)

The method according to Claim 2, further comprising providing a resistance drift factor to the resistance value in accordance with the algorithm.

Claim 4. (Previously

| | |
|---------------------------------|---|
| Presented) | The method according to Claim 1, further comprising generating an externally applied field at the patient. |
| Claim 5. (Previously Presented) | The method according to Claim 4, further comprising using a generator signal for generating the externally applied field, wherein the generator signal is at a different frequency than the temperature measurement signal. |
| Claim 6. (Original) | The method according to Claim 5, wherein the generator signal is used to generate an AC magnetic field. |
| Claim 7. (Original) | The method according to Claim 6, wherein the generator signal is 3 KHz. |
| Claim 8. (Original) | The method according to Claim 7, wherein the temperature measurement signal is 4 KHz. |
| Claim 9. (Original) | The method according to Claim 1, further comprising using a signal processor for measuring the voltage at the position sensor. |
| Claim 10. (Original) | The method according to Claim 9, further comprising determining the resistance value using the signal processor. |
| Claim 11. (Original) | The method according to Claim 10, further comprising determining the temperature value using the signal processor. |
| Claim 12. (Original) | The method according to Claim 11, further comprising performing an ablation procedure at the site with the medical device. |

Claim 13. (Previously Presented)

A method for adjusting for temperature sensitivity of a medical device having a position sensor, the method comprising the steps of:
providing a medical device having a position sensor for providing signals used in determining position and/or orientation coordinates of the position sensor;
determining position and/or orientation coordinates of the position sensor based on the signals provided by the position sensor using a location system;
measuring voltage at the position sensor;
determining a resistance value from the measured voltage;
determining a temperature value at the position sensor based on the resistance value; and
determining a sensitivity at the position sensor based on the temperature value.

Claim 14. (Original)

The method according to Claim 13, further comprising adjusting location information from the position sensor based on the sensitivity.

Claim 15. (Original)

The method according to Claim 14, further comprising adjusting position and orientation coordinates from the position sensor based on the sensitivity.

Claim 16. (Original)

The method according to Claim 15, further comprising determining the temperature value at the position sensor by applying a resistance drift factor to the resistance value.

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| Claim 17. (Original) | The method according to Claim 16, further comprising recalling the resistance drift factor from a memory of a signal processor. |
| Claim 18. (Original) | The method according to Claim 17, further comprising establishing the resistance drift factor from a resistance versus temperature profile of the position sensor. |
| Claim 19. (Original) | The method according to Claim 15, further comprising determining the sensitivity at the position sensor by applying a sensitivity drift factor to the temperature value. |
| Claim 20. (Original) | The method according to Claim 19, further comprising recalling the sensitivity drift factor from a memory of a signal processor. |
| Claim 21. (Original) | The method according to Claim 20, further comprising establishing the sensitivity drift factor from a sensitivity versus temperature profile of the position sensor. |

ix. Evidence Appendix

Not Applicable.

x. Related Proceedings Appendix

Not Applicable.